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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,365	06/23/2006	Bengt Bjellqvist	PU03103	8056
22840 7590 09/29/2009 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855				
EXAMINER				
BALL, JOHN C				
ART UNIT		PAPER NUMBER		
1795				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

melissa.leck@ge.com

Office Action Summary

Application No.

10/584,365

Applicant(s)

BJELLQVIST ET AL.

Examiner

J. CHRISTOPHER BALL

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date 06/23/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. This is the initial Office Action based on the BJELLQVIST application filed as a National Stage Entry Application of the application filed under the Patent Cooperation Treaty on December 15, 2004. The preliminary amendment filed June 23, 2006, is acknowledged and has been entered.
2. Claims 1-17 are currently pending and have been fully considered.

Claim Objections

3. Claims 5, 6, 9, 15, and 17 are objected to because of the following informalities: Claims 5, 9, 15, and 17 recite QAE and/or Q-groups as limitations, however, these terms are not defined within the claims. Claim 6 recites a DEAE-group as a limitation, however, this term is not defined within the claims. For the sake clarity, the terms for which QAE, Q, and DEAE are abbreviations for should be included within the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement.

Regarding claims 1 and 2, RICE discloses a membrane loader for gel electrophoresis, wherein is taught a method for sample application to a gel, comprising:

placing a hydrophilic support (308, Figure 5b) between a cathode (206, Figure 5b) and the cathode side of a gel (Figure 5b), wherein the support can be celluloid, plastic nylon or nitrocellulose (lines 12-15, page 5), which are hydrophilic; and

applying the sample onto the hydrophilic support (lines 2-4, page 5), wherein the hydrophilic support is derivatized with positively charged groups (lines 16-18, page 5).

It is noted by the Examiner that the preamble to claim 1 recites a method for sample application to an acidic interval immobilized pH gradient (IPG) gel, however, since the Applicant defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation (*Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)).

Regarding claim 10, RICE teaches the loader membrane can have a varying thickness and thereby releasably retain more or less sample (lines 22-24, page 8). Therefore, the sample applied can be of any amount including in preparative amounts.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3-6, 8, 9, 11, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement, in view of CARLSSON et al. (US 6,528,322 B1).

Regarding claims 3-6, RICE teaches the limitations of claim 1, as outlined above.

RICE teaches that the support can be positively charged (lines 16-18, page 5), which one of skill in the art would know could be obtained by cation groups. RICE does not explicitly teach cation groups.

However, CARLSSON discloses a method and apparatus for the separation of analytes via a matrix, wherein is taught a ligand/structure that can be introduced to the matrix (Col. 6, lines 19-21), where the ligand/structure comprise ion-exchange functional groups including anion exchangers (inherently cation groups), such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Regarding claims 8 and 9, RICE teaches the limitations of claim 1, as outlined above. RICE additionally teaches that the support can be formed from celluloid materials.

RICE does not explicitly teach the support is made from regenerated cellulose.

However, CARLSSON teaches matrices can be formed from regenerated cellulose (Col. 5, line 47-49), which would extend to the materials from which the ligand/structure can be formed. CARLSSON also teaches the ligand/structure comprise ion-exchange functional groups including anion exchangers such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49), which quaternary ammonium would be logical substitute to a skilled artisan that would yield predictable results.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in forming the support from regenerated cellulose and functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Regarding claim 11, RICE teaches the limitations of claim 1, as outlined above.

RICE does not teach the method as a first step in 2D electrophoresis.

However, CARLSSON teaches a 2D electrophoresis (Col. 3, lines 19-30; Figures 2A-C).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE to make the method the first step in a 2D electrophoresis process as taught by CARLSSON because it allows a better separation means versus a single dimension electrophoresis.

Regarding claims 16 and 17, RICE discloses a sample applicator for an electrophoresis gel (308, Figure 5b). It is noted by the Examiner that the preamble to claim 16 recites a sample application to an acidic interval immobilized pH gradient (IPG) gel, however, since the Applicant defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation (*Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)).

RICE does not explicitly teach the support is made from regenerated cellulose.

However, CARLSSON teaches matrices can be formed from regenerated cellulose (Col. 5, line 47-49), which would extend to the materials from which the ligand/structure can be formed. CARLSSON also teaches the ligand/structure comprise ion-exchange functional groups including anion exchangers such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49), which

quaternary ammonium would be logical substitute to a skilled artisan that would yield predictable results.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in forming the support from regenerated cellulose and functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

9. Claims 7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement, in view of OLECH et al. (US 6,156,182).

Regarding claim 7, RICE teaches the limitations of claim 1, as outlined above.

RICE does not teach an IPG gel.

However, OLECH discloses an immobilized pH gradient gel strip (Abstract), wherein the sample is applied and the gel is rehydrated (Col. 4, lines 58-60), however it has been held selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (*In re*

Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)), so the hydration of the gel before addition of the sample would be obvious to a skilled artisan.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE by utilizing the IPG gel as taught by OLECH because it allows the technique of isoelectric focusing (Col. 1, lines 45-52).

Regarding claims 12 and 13, RICE discloses a kit comprising a positively charged (lines 16-18, page 5) sample applicator (308, Figure 5b) and a gel (220, Figure 5b).

RICE does not teach an IPG gel.

However, OLECH discloses an immobilized pH gradient gel strip (Abstract), wherein the sample is applied and the gel is rehydrated (Col. 4, lines 58-60), however it has been held selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)), so the hydration of the gel before addition of the sample would be obvious to a skilled artisan.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE by utilizing the IPG gel as taught by OLECH because it allows the technique of isoelectric focusing (Col. 1, lines 45-52).

Regarding claim 14, RICE as modified by OLECH teaches the limitations of claim 12.

RICE and OLECH do not teach a specific acidic interval.

However, the IPG acidic interval would be recognized as a result effective variable to one of ordinary skill in the art. The determination of the optimum or workable ranges of said variable might be characterized as routine experimentation (*In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)), and therefore it would be obvious to one of skill to have an acidic interval of pH 3.5-5, among other possible ranges.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement, in view of OLECH et al. (US 6,156,182) as applied to claims 7 and 12-14 above, and further in view of CARLSSON et al. (US 6,528,322 B1).

RICE as modified by OLECH teaches the limitations of claim 12.

RICE and OLECH do not explicitly teach the support is made from regenerated cellulose.

However, CARLSSON teaches matrices can be formed from regenerated cellulose (Col. 5, line 47-49), which would extend to the materials from which the ligand/structure can be formed. CARLSSON also teaches the ligand/structure

comprise ion-exchange functional groups including anion exchangers such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49), which quaternary ammonium would be logical substitute to a skilled artisan that would yield predictable results.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in forming the support from regenerated cellulose and functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JCB
09/22/2009